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EXAMINER

KIM, VICKIE Y 12

ART UNIT PAPER NUMBER

1614

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/929,384

Applicant(s)

ANDERSON, RICHARD ROX

Examiner

Vickie Kim

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-- *Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 22-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 25-29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5811 6) ☐ Other: .

## **DETAILED ACTION**

### ***Election acknowledged***

1. Acknowledgement is made of an election of Groups I (claims 1-21, 25-29) with traverse. Applicant traversed on the ground that the invention I and II are not patentably distinct because they are not obvious variants. The traverse is not persuasive due to the reasons of the record as evidenced by numerous patented document (e.g. US4803069:column 1, lines 10-25 or US6183773:claims 1 and 13 ). For instance, the modification of sebaceous gland can be achieved by materially different product(e.g. chromophore). Furthermore, it is burden to examine all the entire groups because a reference which anticipates the inventions I-II would not render the inventions III-IV obvious, absent ancillary art, and thus, it is undue burden for examiner to perform accurate and quality examination. Thus, the restriction requirement is properly maintained, and made FINAL.

### ***Status of Application***

1. Claims 1-29 are pending. The elected claims 1-21 and 25-29 are presented for the examination. Non-elected claims 22-24 are withdrawn from the consideration.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 11 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 11 and 13 are dependent on claims 11 and

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13, respectively. It is confusing what these instant claims are referring to or by.

Clarification is required.

***Claim Rejections - 35 USC § 102/103***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-21 and 25-29 are rejected under 35 U.S.C. 102(e) /103(a) as being anticipated by, or obvious over Kennedy et al(US 5,955,490).

Kennedy et al teach a method for treating sebaceous gland disorder(including all exocrine glands and associated ducts) such as acne using a photodynamictherapy

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(PDT) comprising administering a topical solution containing 5-aminolevulinic acid(ALA) or a precursor thereof to the patient in an amount sufficient to induce synthesis photosensitizing concentrations of a protoporphyrin IX(PpIX) followed by exposure of skin to light of photoactivating wavelengths, see abstract and example 8 at column 18. It further teaches that effective light source is sunlight or a visible red light which has effective energy wavelength in the range of 400-700nm, preferably 625-640 nm, see column 5, lines 53-58 and column 15, lines 48-50. Although energy dose( $100\text{J}/\text{cm}^2$ ) required by claims 3, it is well known to any skilled artisan that the standard condition ( $630\text{nm}$ ,  $100\text{J}/\text{cm}^2$ ) is applied in photodynamic therapy. When ALA is topically applied into affected skin lesion, ALA is metabolized into PpIX, naturally occurring photosensitizer in vivo, and thereafter exposing the patient to light source activates photosensitizer(PpIX),see example 8 and claims 1-12. It further teaches effective photosensitizer(PpIX)'s accumulation is responsible for the effectiveness of the treatment, takes place in sebaceous glands and associated ducts that are located at least partially within an epidermal surface or within the underlying dermis, such as the pilosebaceous units of the skin, see column 7, lines 5-65. It is also noted that certain limitations recited in the instant claims such as a penetration of skin via a pilosebaceous unit, or modification (or opening) of infundibulum are considered to be inherent where all these elements are naturally occurring when ALA preparation is topically applied to the affected skin area. As to claims 18-20, the limitations(i.e. a diminishment of the said disorders at least for 5-20 weeks) are also encompassed by this reference because all the treatment is aimed for the permanent or longer cessation of diseases, as also

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evidenced by Kennedy, for example, ALA application vanished all clinical evidence of the infection for few months(see column 20, lines 60-63). Thus, all the critical elements required by the instant claims 1-20 are taught by the cited reference.

As to claims 21 and 25-29, Kennedy contemplates specific treatment for sebaceous gland disorders(i.e. acne) in his patent, see column 18, lines 1-40. Kennedy teaches that acne which is frequently associated with bacteria is effectively treated by topical ALA application(e.g.10-20%solution). Permanent cessation of acne should have been encompassed by treatment of acne because the ultimate goal for the acne treatment should be aimed to permanent cessation of acne. One would have envisaged that standard condition has been applied in Kennedy's PDT since there is no specific restriction required. All the critical elements are taught by the claims, and thus the claims are anticipated.

Even if every elements and steps in the claims has not exactly mentioned by Kennedy's reference, one would have envisaged, otherwise the claimed minor variations including the selection of optimal dosages, routes of administration, duration of therapy or variable applications in order to determine the most effective treatment is well within the skilled level of artisan having ordinary skill in the art, and is obvious.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-21 and 25-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giersccky(WO95/07077) in view of Kennedy et al (US 5955490) and Tankovich (US 5713845).

WO'077 teaches a stable photochemotherapeutic composition containing 5-aminolevulinic acid(ALA) which penetrates the skin layers and is used effectively in the treatment of disorders of internal and external body surface(e.g. sebaceous glands), see abstract and page 7, 3<sup>rd</sup> paragraph.

WO'077 teaches an effective skin-penetrating topical application of ALA (5-30%) which is inducing the synthesis of extremely potent photosensitizer, protoporphyrin IX(PpIX), so that it can be built-up locally at the site of the action by exposing the site of application to the effective photoactivating light including lasers (e.g. 500-700 nm, 40-100J/cm<sup>2</sup>), see claims and pages 3, 9-10. WO'077 teaches most elements required by the instant claims. . It is also noted that certain limitations recited in the instant claims such as a penetration of skin via a pilosebaceous unit, or modification (or opening) of infundibulum are considered to be inherent where all these elements are naturally occurring when ALA preparation is topically applied to the affected skin area.

Although WO'077 teaches various disorders(e.g. bacterial, psoriasis or actinic keratoses) including internal and external body surface including sebaceous glands with ducts(empty), acne as not been specifically mentioned in his patent as being a sebaceous gland disorder. Applicant's claims also have minor differences which are not taught in WO'077, for example, a diminishment of disorders for a period of at least 5-20 and ultrasound to drive the ALA into the spaces (recited in claims 15, 18).

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As mentioned in 102 rejection, Kennedy et al(US'490) teaches a photochemotherapy of 5-aminolevulinic acid(ALA) and treatment of sebaceous gland disorder(including all exocrine glands and associated ducts) such as acne, comprising topically applying ALA into skin lesion wherein ALA induces PpIX in vivo, and thereafter exposing the patient to light capable of photoactivating PpIX, naturally occurring photosensitizer, see example 8 and claims 1-12.

Tankovich(US'845) teaches a process for laser assisted drug delivery where the active drug used is ALA( $\delta$ -aminolevulinic acid) topical preparation used for treating various skin disorders, see abstract, column 3(line 12) and claim 28. The laser assisted drug delivery by infiltration of drugs through the skin(spaces of the skin section) which can be increased by forcing the drug into hair follicles, see column 1, lines 45-55. It further teaches that the spaces is within or adjacent to sebaceous glands and the drug delivery of PDT sensitizer including ALA can be maximized.

When these references are taken together, it would have been obvious to any ordinary skill in the art to incorporate laser or other aids(e.g.ultrasound) into the PDT therapy so that the lowest effective concentration of ALA via topical application is delivered to the targeted site of action. One would have motivated to do so by modifying Giersccky in view of Kennedy and Tankovich to maximize the efficiency of delivery system via effective penetration and delivery so that lowest active drug concentration(ALA) is used to induce maximum amount of the potent photosensitizer, PpIX synthesized and built-up in the localized spaces to maximize the therapeutic effects by exposing the site of action without the any undesirable side effect. Again, the



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minor variations including the selection of optimal dosages, routes of administration, or variable applications by modification of any conventional knowledge in order to determine the most effective treatment is well within the skilled level of artisan having ordinary skill in the art, and is obvious.

One would have been motivated to combine these references and make the modification because they are drawn to same technical fields (constituted with same (or similar) ingredients and share common utilities), and pertinent to the problem which applicant concerns about. MPEP 2141.01(a).

### ***Conclusion***

1. No claim is allowed.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,  
Patent examiner  
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